

Application No: 10/782,827
PROPOSED AMENDMENT FOR REVIEW ONLY

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the claim amendments and following remarks. Claims 23-25 have been added. Claims 1, 19, 20, and 21 have been amended. Currently, claims 1-25 are pending in the present application of which claims 1, 19, 21, and 23 are independent. No new matter has been added.

Claims 1-17 and 19-22 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not provide enablement for treating patients with all disorders marked by a loss of pigmentation. Claims 1-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,985, 443 to Montes, in view of "Vitiligo and Other Hypomelanoses of Hair and Skin", 1983 to Ortonne et al. (hereinafter "Ortonne"), "International Journal of Artificial Organs 2000", 23(8), 568, to Kolyadenko et al. (hereinafter "Kolyadenko") and "Alternative Medicine Review" 1997, 2(2), pages 116-127, to Kelly. The above rejections are respectfully traversed for at least the reasons set forth below.

Claim Rejection Under 35 U.S.C. §112

Claims 1-17 and 19-22 were rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for treatment of vitiligo or grey hair, allegedly does not provide enablement for treating patients with all disorders marked by a loss of pigmentation. Claims 1 and 19 have accordingly been amended to replace the language "disorders marked by a loss of pigmentation" with the language "vitiligo or grey hair." Claim 21 has also been amended to

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replace the language "treating disorders marked by a loss of pigmentation" with the language "stimulating the proliferation of melanocyte cells." The specification clearly provides support and enablement for stimulating the proliferation of melanocyte cells in Paragraphs [0017] and [0021]. The Examiner is therefore respectfully requested to withdraw the rejection of claims 1, 19, and 21, as well as their dependent claims 2-17, 20, and 22.

Claim 20 was rejected under 35 U.S.C. §112, second paragraph as having insufficient antecedent basis for the limitation "said female patient" in the claim. Claim 20 has accordingly been amended to depend from Claim 19, which contains the correct antecedent basis "a female patient," as noted by the examiner.

Claim Rejection Under 35 U.S.C. §103

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in MPEP § 706.02(j):

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

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Therefore, if the above-identified criteria are not met, then the cited reference(s) fails to render obvious the claimed invention and, thus, the claimed invention is distinguishable over the cited reference(s).

Claims 1-22 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,985,443 to Montes, in view of "Vitiligo and Other Hypomelanoses of Hair and Skin", 1983 to Ortonne et al. (hereinafter "Ortonne"), "International Journal of Artificial Organs 2000", 23(8), 568, to Kolyadenko et al. (hereinafter "Kolyadenko") and "Alternative Medicine Review" 1997, 2(2), pages 116-127, to Kelly. This rejection is respectfully traversed because Montes, Ortonne, Kolyadenko and Kelly, considered singly or in combination, fail to teach or suggest the claimed invention as set forth in claims 1, 19, 21, and their dependents.

Montes discloses treatment of vitiligo with vitamin B12; folic acid; and vitamin C.

Ortonne and Kolyadenko each disclose treatment of vitiligo or skin depigmentation with copper. Ortonne also teaches use of pantothenic acid.

Kelly shows treatment of vitiligo with oral HCl salts administered at mealtimes; a connection between gastric acidity and skin diseases is drawn.

Claims 1, 19 and 21 each recite administering an effective amount of vitamin B12, copper, folic acid, and vitamin C to a patient suffering from vitiligo or grey hair. Claim 19 additionally recites treatment with copper while a female patient is not undergoing menses, but not while a female patient is undergoing menses. Claim 21 additionally recites a step of exposing depigmented skin or hair of the patient to the sun or to ultraviolet light. The Official Action appears to admit that Montes does not teach all the elements of the independent claims;

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specifically, copper, along with other ingredients recited in the dependent claims, is not taught by Montes for treating vitiligo.

The Official Action states that "it would have been obvious to one of ordinary skill in the art... to add administering an effective amount of: copper... to a patient suffering from a loss of pigmentation, as suggested by the combined teachings of Ortonne et al., Kolyadenko et al., and Kelly, in the method of Montes..." The Official Action alleges that one of ordinary skill in the art would have been motivated to do this, not because of any teachings within the cited art, but rather because "the idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980).

The applicant, through his representative, respectfully disagrees with this position. First, of all, it is worth noting that *In re Kerkhoven* was not directed to an invention in the pharmaceutical arts. This is important because pharmaceutical compositions are subject to a wide variety of complicated interactions within the human body. While it is possible that two ingredients may exert a synergistic effect in treatment of a particular condition, it is also possible that combination of two ingredients, each effective against a particular condition, will show no increase in effectiveness when they are combined. It is well known that combinations of pharmaceutical ingredients can be less effective than either ingredient would be individually. In light of this, combination of two compositions, each effective against a medical condition such as vitiligo, to prepare a third composition cannot be considered *prima facie* obvious, in the absence of some teaching that such a composition will be safe and/or effective. The art cited by the examiner provides no such teaching, and the combination of art relied upon by the examiner is

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therefore merely hindsight reconstruction in light of the invention disclosed and claimed in the current application. At most, the combination made in the Official Action is merely "obvious to try." This is not dissimilar to the fact pattern in the case *In re Geiger*, as cited in MPEP Section 2144.06:

Based upon the prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art..., the board held that it would have been *prima facie* obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive.... Appellant argues ... hindsight reconstruction or at best, ... 'obvious to try'....

In re Geiger
815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987)

The court rejected a standard of "obvious to try" as improper grounds for a § 103 rejection:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination... At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known... agents. However, this is not the standard of 35 U.S.C. § 103.

In re Geiger
815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987)

At least by virtue of Montes's, Ortonne's, Kolyadenko's, and Kelly's failure to teach or suggest the combination of copper with vitamin B12, folic acid, and vitamin C, a *prima facie* case of obviousness has not been established under 35 U.S.C. § 103.

Additionally, with regard to claim 19, the examiner asserts that "the method of treating disorders marked by a loss of pigmentation is obvious whether administered to a female undergoing menses or not undergoing menses." However, the examiner has failed to provide any teaching that would lead one of ordinary skill in the art to administer copper to a female patient with vitiligo or grey hair during one part of her menstrual cycle, but not during another

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part of her menstrual cycle. Therefore, a *prima facie* case of obviousness has not been established under 35 U.S.C. § 103.

Accordingly, the Examiner is respectfully requested to withdraw the rejection of claims 1, 19, and 21. Claims 2-18 depend from allowable claim 1; claim 20 depends from allowable claim 19; and claim 22 depends from allowable claim 21; these dependent claims are also allowable over Montes in view of Ortonne, Kolyadenko and Kelly at least by virtue of their dependencies.

Newly Added Claims

Claims 23-25 have been added. Claim 23 includes elements similar to the elements in claim 1 and therefore is allowable over the prior art of record for similar reasons. Claims 24 and 25 depend upon claim 23 and are allowable at least by virtue of their dependencies. Therefore, the Examiner is respectfully requested to allow claims 23-25.

Conclusion

In light of the foregoing, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

While we believe that the instant amendment places the application in condition for allowance, should the Examiner have any further comments or suggestions, it is respectfully requested that the Examiner telephone the undersigned attorney in order to expeditiously resolve any outstanding issues.

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Respectfully submitted,
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